



**DEPARTMENT OF VETERANS AFFAIRS
Veterans Health Administration
Washington DC 20420**

IL 10-2011-008

August 3, 2011

UNDER SECRETARY FOR HEALTH'S INFORMATION LETTER

ELECTRONIC CIGARETTES (E-CIGARETTES)

1. Purpose. This Veterans Health Administration (VHA) Information Letter provides Information on electronic cigarettes, also known as e-cigarettes or electronic nicotine delivery systems (ENDS).

2. Background

a. Electronic cigarettes or e-cigarettes were developed and patented by the RUYAN Group in Beijing, China in 2004. They are still manufactured largely in China, and they are sold and distributed in the United States largely through internet sales and shopping mall kiosks. E-cigarettes are designed to simulate the appearance and sensory experience of smoking conventional tobacco leaf-based cigarettes.

b. The common design characteristics of electronic cigarettes include: a cartridge that contains a liquid form of nicotine in varying levels of concentration in addition to a humectant, such as propylene glycol; a plastic tube into which the cartridge is inserted and the user inhales; and an electronic heating element. The user clicks a button that activates the heating element, a puff of vaporized nicotine is released and a light emitting diode at the end of the tube illuminates to resemble a lit cigarette. Electronic cigarettes have been widely marketed as alternatives to conventional cigarettes for use in smoke-free zones and as a "safer" alternative to smoking.

c. The World Health Organization (WHO) noted in 2009 that e-cigarettes "pose significant public health issues and raise questions for tobacco control policy and regulation." E-cigarette manufacturers have not provided complete information on the chemicals used in the manufacturing process or chemicals that are synthesized during the vaporization process that occur during e-cigarette use. The WHO went on further to state, "there is little or no data available on the emissions, their health effects have not been studied, and their marketing and use could undermine public smoking bans, which are important public health interventions." Because of these concerns, as well as concerns about the safety of electronic cigarettes, the sales, marketing, and import of these products are banned in a number of countries including Australia, Brazil, Canada, Denmark, Netherlands, Norway, Panama, and Singapore.

d. The Family Smoking Prevention and Tobacco Control Act of 2009 provides for regulation of new reduced-harm tobacco products through the Food and Drug Administration (FDA) Center for Tobacco Products, while medicinal nicotine products (such as nicotine replacement therapy (NRT)) are regulated through the FDA Center for Drug Evaluation and Research. As electronic

cigarettes are not conventional tobacco products and manufacturers have not submitted applications for evaluation or approval as medical devices or pharmaceuticals, they do not currently fall under FDA or other regulatory agencies. On April 25, 2011, the FDA announced that it was “developing a strategy to regulate this emerging class of products under the Family Smoking Prevention and Tobacco Control Act.”

e. In 2009, the FDA conducted a laboratory analysis of two widely-marketed e-cigarettes and their findings provided evidence that these products expose users to harmful chemical ingredients, including many of the same toxic and carcinogenic compounds found in conventional cigarettes. The analysis also found that levels of nicotine contained in the samples were inconsistent with the labeling, including higher levels than indicated in some instances.

f. Additional safety concerns about these products have also been described. These include concerns about addiction potential and concerns about the potential for adverse events, such as nicotine poisoning, if the concentrated liquid nicotine found in the refill cartridges is accidentally ingested or spilled on the skin. There are also concerns about electronic cigarettes as they potentially deliver significant amounts of nicotine for absorption directly to the lungs.

g. Electronic cigarettes need not be confused with NRT products that have been approved by the FDA for smoking cessation. NRT therapies include nicotine-containing skin patches, gum, lozenges, oral inhalers, and nasal sprays that have demonstrated well-established safety records and proven efficacy through controlled clinical trials. None of the currently-approved NRT products delivers nicotine systematically to the lungs. Even with the use of the nicotine “inhaler,” more than 90 percent of the nicotine is delivered and absorbed in the oral cavity and very little reaches the lungs.

3. Recommendations

a. It is recommended that health care providers share information about the lack of information regarding the safety of these consumer products and to inform their patients (and staff) about the difference between these products and FDA-approved NRT. As recommended by the WHO and FDA, health care professionals need to advise their patients that E-cigarettes should not be used as a tobacco cessation aid. Instead, providers need to provide information about the efficacy of behavioral counseling and FDA-approved medications, such as NRT, as evidence-based cessation treatment. **NOTE:** *For additional guidance on the use of FDA-approved smoking cessation medications, go to <http://vaww.publichealth.va.gov/smoking/clinical.asp>. This is an internal Web site and is not available to the public.*

b. It is recommended that any local Department of Veterans Affairs (VA) medical facility or VISN-level policies, which are developed on the issue of use of E-cigarettes in areas that are currently smoke-free, be in accordance with this guidance from the WHO, which states that electronic cigarettes “not be exempted from ‘clean air’ laws.” Until additional safety information about these products is available and adequate evidence is provided to ensure regulatory authorities that use of the product will not expose nonusers to toxic emissions, places in which cigarette smoking is restricted need to also restrict the use of e-cigarettes.

4. References

- a. World Health Organization. "WHO Study Group on Tobacco Product Regulation: Report on the Scientific Basis of Tobacco Product Regulation." WHO Technical Report Series. 2009.
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- d. Kuehn BM. FDA: Electronic cigarettes may be risky. Journal of the American Medical Association: 2009; 302 (9): 937.
- e. Cobb NK, Byron MJ, Abrams DB, Shields PG. Novel nicotine delivery systems and public health: The rise of the "E-cigarette". American Journal of Public Health 2010;100 (12): 2340-2342.
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- g. Wollscheid KA, Kremzner ME. Electronic cigarettes: Safety concerns and regulatory issues. American Journal of Health Systems Pharmacy 2009;66:1740-1742.
- h. Fiore MC, Jaen CR, Baker TB, et al. *Treating Tobacco Use and Dependence: 2008 Update*. Clinical Practice Guideline. Rockville, MD: U.S. Department of Health and Human Services. Public Health Service. May 2008.

5. Inquiries. The Public Health Strategic Health Care Group (10P3B) is responsible for the contents of this Information Letter. Questions may be directed to the Director of Public Health Policy and Prevention at publichealth@va.gov or (202) 461-1040.

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Distribution: E-mailed VHA Publications Distribution List 8/4/2011